WALSH PIZZI O'REILLY FALANGA

THREE GATEWAY CENTER
100 Mulberry Street, 15th Floor
Newark, NJ 07102
T: 973.757.1100
F: 973.757.1090
WALSH.LAW

Liza M. Walsh
Direct Dial: (973) 757-1101
lwalsh@walsh.law

September 7, 2022

VIA ECF
Hon. Julien Xavier Neals, U.S.D.J.
United States District Court for the District of New Jersey
Martin Luther King Jr. Bldg. & U.S. Courthouse
50 Walnut Street
Newark, New Jersey 07102

Re: *Mylan Pharms. Inc. v. Teva Pharms. Indus. Ltd., et al.*, Civil Action No. 2:21-cv-13087 (JXN-JSA)

***In re Copaxone Antitrust Litigation*, Civil Action No. 2:22-cv-1232 (JXN-JSA)**

Dear Judge Neals:

This firm, along with Goodwin Procter LLP, represents Teva Pharmaceutical Industries Ltd., Teva Pharmaceuticals USA, Inc., Teva Neuroscience, Inc., and Teva Sales & Marketing, Inc. (collectively, "Teva") in the above-referenced matters. We are writing to respond to the letters submitted by the Direct Purchaser Plaintiffs ("DPPs") and Third-Party Payor Plaintiffs ("TPPs") (collectively, "Class Plaintiffs") in Docket No. 2:22-cv-1232 on August 26, 2022 (ECF No. 73) ("Class Letter"), and by Mylan Pharmaceuticals, Inc. in Docket No. 2:21-cv-13087 on August 29, 2022 (ECF No. 89) ("Mylan Letter"). Both letters pertain to the decision in *In re Suboxone (Buprenorphine Hydrochloride and Naloxone) Antitrust Litig.*, No. 13-md-2445, ECF No. 812 (E.D. Pa. Aug. 22, 2022).[1] Contrary to Class Plaintiffs' and Mylan's submissions, *Suboxone* provides no basis for any of the claims asserted by the Class Plaintiffs or Mylan to survive dismissal.

The claims in *Suboxone* were exclusively directed at a "product hop" theory of liability, with plaintiffs asserting that the brand manufacturer (Reckitt Benckiser) forced consumers to shift from a product that faced generic competition (Suboxone tablets) to a similar product that faced no generic competition (Suboxone film). There were no claims challenging a brand manufacturer's efforts to compete after generic entry for both available formulations of a product. Moreover, and in significant contrast to the allegations against Teva regarding Copaxone, the court found sufficient evidence that the defendant engaged in a "hard switch" scheme by withdrawing a product that faced generic competition from the market and forcing consumers to switch to a new patent-protected product. Exhibit A, at 46. Here, by contrast, Class Plaintiffs and Mylan ***concede*** that Teva did ***not*** engage in a hard switch, as the original Copaxone 20 mg product has remained available to consumers at all times. *See* Mylan Br. in Opp. to Defs.' Mot. to Dismiss and Mot. to Strike at 17 & n.8, No. 21-cv-13087, ECF No. 56 ("Mylan Opp."); Direct Purchaser Pls.' Opp. to Defs.' Mot. to Dismiss at 44, No. 22-cv-1232, ECF No. 50 ("DPP Opp.").

[1] The *Suboxone* decision is attached as **Exhibit A** to each of the Class Plaintiffs' and Mylan's letters.

As explained below, these key distinctions between these cases and *Suboxone* undermine Class Plaintiffs' and Mylan's attempt to draw support for their claims from the *Suboxone* decision.

1. *Suboxone* does not support the attempts by Mylan and the DPPs to establish anticompetitive conduct based on an alleged "product hop" from Copaxone 20 mg to Copaxone 40 mg. (TPPs do not allege a product hop.) As Teva has explained, "courts have drawn 'an important distinction between hard and soft switches,'" holding that only hard switches—in which consumer choice is eliminated because a product is pulled from the market—may raise potential competitive concerns. *See* Br. in Supp. of Defs.' Mot. to Dismiss and Mot. to Strike at 31, No. 21-cv-13087, ECF No. 55-1 ("Teva (Mylan) Br.") (quoting *In re Asacol Antitrust Litig.*, 233 F. Supp. 3d 247, 269 (D. Mass. 2017)); *see also* Br. in Supp. of Defs.' Mot. to Dismiss at 33-34, No. 22-cv-1232, ECF No. 40-1 ("Teva (Direct Purchaser) Br."). The *Suboxone* case falls on the "hard switch" side of the line, while the claims here do not.

The plaintiffs in *Suboxone* argued that the defendant violated federal and state antitrust laws by developing a film version of its Suboxone product that was already available in tablet form and then taking steps to shift the market to the film product. Exhibit A, at 6-15. Critically, Reckitt did not simply introduce the film version of Suboxone; it announced its intent to withdraw the tablet from the market and then it did so. *Id*. at 36. This product withdrawal "effectively forc[ed] patients that depended on Suboxone to switch to the film version," and thereby reduced consumer choice. *Id*.; *see id*. at 30 ("[S]uch conduct could be deemed to have actually deprived consumers of choice as it resulted in a planned removal of the tablet prior to generics coming into the market"). Moreover, even leading up to the withdrawal of Suboxone tablets, Reckitt took actions to restrict consumer access to the product: it "ended rebates on tablets," ended a patient assistance program for tablets, and encouraged insurers to "disadvantage tablets" by downgrading its formulary position and blocking patients from using tablets unless they tried the film product first. *Id.* at 11, 14. And Reckitt did not merely extoll the virtues of its film product, but described the tablets to doctors and patients as unsafe. *Id.* at 54. Based on all of this, the court concluded that a reasonable fact finder could conclude that Reckitt's conduct had "deprived consumers of choice," forcing them to switch to the film version of Suboxone. *Id.* at 30.

In sharp contrast, DPPs and Mylan do not plausibly allege that Teva's introduction of Copaxone 40 mg reduced consumer choice. As noted, they do not allege that Teva ***ever*** withdrew Copaxone 20 mg or even threatened to do so. Nor do they allege that Teva restricted access to its "Shared Solutions" patient-support service for patients who opted to stick with Copaxone 20 mg or tried to get insurers to disadvantage Copaxone 20 mg on their formularies. Rather, Mylan's and DPPs' allegations center on Teva's alleged efforts to promote access to its new 40 mg product and its more convenient dosing regimen by attractively pricing the new product and insisting that Pharmacy Benefit Managers ("PBMs") include the 40 mg product on their formularies to retain rebates for the 20 mg product. *See* Complaint ¶¶ 119-30, No. 21-cv-13087, ECF No. 1 ("Mylan Compl."); Complaint ¶¶ 120-31, No. 22-1232, ECF No. 2 ("DPP Compl."). These alleged efforts to introduce and promote a new product ***increased*** consumer choice and are therefore fundamentally different in kind from the evidence of a hard switch and related activities at issue in *Suboxone*.

2. Class Plaintiffs and Mylan are also wrong to argue that *Suboxone* supports their approach to basing liability on an overall "scheme" consisting of independently lawful activity. In fact, the *Suboxone* court recognized that, while it should "keep the larger scope" of an alleged scheme in context, it is "appropriate to consider the individual components of the scheme and whether those components could constitute anticompetitive conduct." Exhibit A, at 46 (quotation

marks omitted). The court also agreed that courts must be skeptical of antitrust claims premised on "a number of perfectly legal acts." *Id*. at 47 (quotation marks omitted). Evidently persuaded by this reasoning, Mylan now ***concedes*** "the rule that a monopolization scheme contain ***at least some*** independently anticompetitive conduct" to be viable. Mylan Letter at 3 n.2 (emphasis added). Teva made this exact point previously, and cited an earlier decision in the Suboxone litigation for support. *See* Reply Br. in Supp. of Defs.' Mot. to Dismiss and Mot. to Strike at 3, No. 21-cv-13087, ECF No. 57 ("Teva (Mylan) Reply Br.") (citing *In re Suboxone Antitrust Litig.*, 2017 WL 3967911, at *8 n.10 (E.D. Pa. Sept. 8, 2017)).

Mylan and the Class Plaintiffs nonetheless try to argue that certain statements in *Suboxone* describing the need to consider the aggregate effect of alleged conduct contradict Teva's position, but they do so only by mischaracterizing Teva's argument. Teva did not argue that allegations must be disregarded unless each alleged action is "independently anticompetitive and exclusionary." Mylan Letter at 2; *see also* Class Letter at 2. Rather, Teva explained that it is improper to rely on a "scheme" theory to undermine established limits on antitrust liability—conduct that is immune from antitrust scrutiny (*e.g.*, under the *Noerr-Pennington* doctrine), or is *per se* procompetitive (*e.g.*, above-cost discounting), or did not cause the plaintiff to suffer any antitrust injury, does not suddenly become actionable when lumped in with other lawful conduct. *See* Teva (Mylan) Reply Br. at 2-6. "Nothing plus nothing times nothing still equals nothing." *Zenith Radio Corp. v. Matsushita Elec. Indus. Co.*, 513 F. Supp. 1100, 1311 (E.D. Pa. 1981). The *Suboxone* decision is entirely consistent with this understanding of the law, and the Class Plaintiffs' and Mylan's attempts to extend the court's reasoning about the aggregate effects of a defendant's conduct in the case of an independently actionable hard switch to their concededly different allegations here falls short. *See* Exhibit A, at 44 (explaining that concerns about synergistic effects of conduct were "particularly applicable" in the context of a hard switch).

3. Class Plaintiffs and Mylan fare no better in their effort to draw support from *Suboxone* for their attempts to premise antitrust liability on Teva's alleged false statements about a competitor. In *Suboxone*, the court recognized that "false claims are generally deemed not actionable because such false advertising simply sets the stage for competition … and provides an opportunity for a competitor to counter with its own advertising[.]" Exhibit A, at 58. In concluding that Reckitt's alleged false statements about the safety of Suboxone tablets could support a product-hop claim, the *Suboxone* court stressed that Reckitt's potential competitors were uniquely disabled from engaging in counter-speech because "there were no generic products" on the market at the time. *Id*. By contrast, Class Plaintiffs and Mylan allege that some Teva sales representatives supposedly made false statements about Mylan's generic product ***after*** Mylan and Sandoz had entered the generic market and could engage in their own marketing efforts. *See* Mylan Compl. ¶¶ 132, 134; DPP Compl. ¶ 158.[2] Notably, Teva is not alleged to have made false statements to facilitate a product hop. Moreover, whereas the *Suboxone* court reasoned that doctors might have relied on Reckitt's representations, those misrepresentations not only were insulated from counter-speech but related to Reckitt's ***own product***. Exhibit A, at 57. Nothing in *Suboxone* suggests that doctors blindly rely on a pharmaceutical company's characterization of its ***competitor's*** product, which is what is at issue here. *See* Teva (Direct Purchaser) Br. at 42.

[2] Mylan also alleges that Teva's dispense-as-written campaign began before the FDA approved Mylan's generic, but Mylan alleges no plausible basis for deeming Teva's alleged statements false before the FDA approved its product. *See* Teva (Mylan) Br. at 38-39.

4. The *Suboxone* court's discussion of the price-cost test also does not aid Class Plaintiffs or Mylan. *See* Class Letter at 2; Mylan Letter at 5. In *Suboxone*, the court concluded that the price-cost test did not apply to allegations that Reckitt effected a product hop by pricing the tablet higher than film because price was not the "predominant mechanism of exclusion" with respect to the alleged product hop. *See* Exhibit A, at 50-53. But that outcome is unremarkable and consistent with Teva's position: Teva has not relied on the price-cost test to defend against product-hop allegations, conduct that plainly relies on the hard switch itself, not pricing, as the predominant mechanism of exclusion.[3] Rather, Teva has invoked the price-cost test in relation to Class Plaintiffs' and Mylan's theories that Teva used rebates and other discounts to incentivize PBMs, pharmacies, and patients to favor Copaxone over generic alternatives because they preferred the pricing terms. *See, e.g.*, Teva (Direct Purchaser) Br. at 25; Teva (Mylan) Br. at 44. *Suboxone*'s conclusion that pricing activity can form part of a product-hop claim alleging a hard switch without implicating the price-cost test is irrelevant to whether the price-cost test governs claims of liability premised on Teva's granting of rebates and discounts to PBMs, pharmacies, and consumers to compete against generic versions of both Copaxone 20 mg and 40 mg by offering favorable pricing terms and reducing patients' out-of-pocket costs for both of those products.

5. Finally, *Suboxone* does not support Class Plaintiffs' or Mylan's allegations that Teva's alleged rebates to PBMs for preferential formulary placement for Copaxone are anticompetitive. Class Letter at 2. The portion of *Suboxone* that the Class Plaintiffs cite to support their contrary argument merely concludes that *Noerr-Pennington* does not immunize all of Reckitt's efforts to obtain preferential formulary placement because Reckitt paid rebates to private healthcare payors in addition to Medicaid. Exhibit A, at 69-70. The court did not hold that rebates to private healthcare payors are independently unlawful, and ultimately concluded that it did not need to rely on a theory involving rebates at all to find that the remaining evidence concerning Reckitt's hard-switch product hop was sufficient to survive summary judgment.

* * * * *

We thank the Court for its ongoing attention to this matter and are available should Your Honor or Your Honor's staff have any questions or need anything further.

Respectfully submitted,

s/Liza M. Walsh

Liza M. Walsh

cc: Counsel of Record (via ECF and Email)

[3] The problem for DPPs and Mylan in relation to their challenges to Teva's introduction of the 40 mg product is instead the absence of customer coercion since there was no hard switch.